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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,540	12/11/2001	Nicholas Ling	690068.405C3	4186

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/015,540

Applicant(s)

LING ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-34, 73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-34, 73, 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

1. Claims 30-34,73,74 are pending.
2. Double-patenting rejection is withdrawn in view of submission of Terminal Disclaimer directed to US Patents 6,369,033, 6,489,299, and 6,740,638.

Claim Rejections - 35 USC § 103.

3. Claims 30-34, 73, 74 remain rejected under 35 U.S.C. § 103 as obvious over Martin et al. in view of Nishimoto et al. The rejection is restated as follows, and applicants arguments are addressed.

Martin et al teaches peptides comprising residues 88-100 of human myelin basic protein with the lysine at residue 91 altered to be Ala. Note that because of a different numbering system, the Martin et al article's residues 88-100 correspond to the same fragment of MBP as applicants' residues 87-99. The peptides are synthesized by solid phase synthesis. See, e.g., page 1360, column 1, fourth full paragraph, and page 1362, Figure 3, peptide A1a5 (or Ala5). With respect to claim 74, because the peptides of the Martin et al article were used in *in vitro* cell cultures, inherently they must have been combined with a physiologically acceptable carrier or diluent.

Sequence of the referenced Ala5 is compared to MBP fragment (with residue 91 underlined):

VHFFANIVTPRTP (Ala5)

VHFFKNIVTPRTP... (MBP)

Thus, the referenced peptide analog reads on the instantly claimed analog, except teaching substituting of at N- and C-terminal residues from L- to D - isomers.

Nishimoto teaches that replacement of an L-amino acid residue with the corresponding D- isomer is a standard way of rendering the polypeptide less sensitive to proteolysis. See col. 15, line 2.

As the referenced analogs are intended to be used for pharmaceutical purposes, such as treatment of multiple sclerosis, it would have been obvious to an artisan at the time the invention was made to be motivated to alter the terminal amino acid residues of MBP peptide analogs from L- to D-isomers to reduce proteolysis and thus to increase stability of the analogs.

Response to arguments

Applicant argues that the peptides described by Martin do not include residue 86. Examiner agrees with this. However, the claims do not require presence of residue 86; rather, the claims are directed to peptide analogue comprising any seven consecutive residues selected from residues of 86-99. The analog described in Martin satisfies this limitation.

Further, applicant seem to argue that an artisan would not be motivated to substitute Lys for Ala at position 91. No motivation is needed for this, because Martin et al already produced this analog. The obviousness rejection addresses not the replacement of residue at position 91, but replacement of N- and C- terminal residues.

With respect to the latter, applicant argues that such replacements may not be beneficial for inhibitory effect of a peptide analog. However, the motivation to replace residues from L- to D – isomers provided by Nishimoto reference is to reduce proteolysis and thus to increase stability of the analogs, not to modify the activity.

The rejection is maintained.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb